Paper No. 54

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte DAN W. URRY

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Appeal No. 1999-0623
Application No. 08/316,802

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 4-8, 10-16, 18-23, 26, and 28-38. Claims 39 and 40 are objected to as dependent on a rejected claim[1]. Claims 1, 2, 9, 17, 24 and 25 are canceled. The status of claims 3, 27, 41 and 42 is unclear from the administrative file.

[1] The objection of claims 39 and 40 is a petitionable, rather than an appealable matter. Accordingly, the objection of claims 39 and 40 is not properly before this panel on appeal. Therefore, we will not address the merits of this objection. In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479-480 (CCPA 1971).

Appellant states (Brief[2], page 2) that "[c]laims 3 and 27 … were canceled and rewritten[3] as independent claims 41 and 42, which have been indicated in the Advisory Action[4] of May 11, 1998, to be [a]llowed." The May 11, 1998 Advisory Action states that "[u]pon the filing of an appeal, the proposed amendment will be entered." However, on the first page of appellant's response under 37 CFR § 1.116[5], the examiner wrote the phrase "DO NOT ENTER" above the date and his initials. As a result, the administrative file, does not reflect the entry of appellant's amendment, contrary to the direction provided in the May 11, 1998 Advisory Action. No part of the Answer[6], including the "Status of Claims" section address claims 3, and 27. Therefore these claims are pending, free from rejection and are not before us on appeal.

The examiner does not include claims 41 and 42 in any statement of a rejection. Instead, the examiner states (Answer, page 4) that "contrary to the advisory, paper #48, … claims 41 and 42 may still fail the requirements of 35 U.S.C. [§] 112 because the polymer may comprise nonapeptides for which a sequence has not been delimited." We do not consider the examiner's comments a statement of a rejection regarding claims 41 and 42. Furthermore, as discussed, supra, claims 41 and 42 were not entered into this record. Therefore, claims 41 and 42 are not properly before us for review.

Claims 26 and 28 are illustrative of the subject matter on appeal and are reproduced below:

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[2] Paper No. 50, received June 12, 1998.
[3] In Paper No. 47, received March 20, 1998.
[4] Paper No. 48.
[5] Paper No. 47, received March 20, 1998.
[6] Paper No. 51, mailed September 1, 1998.

26. A drug delivery composition capable of selective release of said drug into a preselected physiological environment, comprising:

(1) a synthetic bioelastic polypeptide polymer comprising repeating elastomeric units selected from the group consisting of bioelastic pentapeptides, tetrapeptides, and nonapeptides, wherein said repeating units comprise amino acid residues selected from the group consisting of hydrohobic amino acid and glycine residues and wherein said repeating units exist in a conformation having a ß-turn; and

(2) a drug retained by said polymer;

wherein said polymer is selected to be in a first contraction state, selected from the group consisting of contracted and relaxed bioelastomer states, when contacted with a physiological environment present in a human or animal to whom said composition is administered and wherein said polymer contains a reactive functional group that undergoes a reaction, either in the presence of said physiological environment or when said polymer is transported by a natural process in said human or animal to a location having a different physiological environment, to produce a second functional group, wherein the presence of said second functional group in said polymer causes said polymer to switch to the other of said contraction states, thereby making said drug available for release from said matrix into said preselected physiological environment.

28. The composition of claim 26 wherein said polypeptide comprises repeating units of the formula aP?OG or VP?d, wherein:

V is a peptide-forming residue of L-valine;
P is a peptide-forming residue of L-proline;
G is a peptide-forming residue of glycine;
α is a peptide-forming residue of L-valine, L-leucine, L-isoleucine, L-phenylalanine or an ionizable peptide-forming residue selected from the group consisting of the residues of L-Glu, L-Asp, L-His, L-Lys, L-Tyr, and other ionizable peptide-forming L-amino acids;
? is a peptide-forming residue of glycine or a peptide-forming residue of D-Glu, D-Asp, D-His, D-Lys, D-Tyr, and other ionizable peptide-forming D-amino acids;
O is a peptide-forming residue of L-valine, L-leucine, L-isoleucine, L-phenylalanine or an ionizable peptide-forming residue selected from the group consisting of the residues of L-Glu, L-Asp, L-His, L-Lys, L-Tyr[7], and other ionizable peptide-forming L-amino acids;

[7] We note the following typographical error in appellants' appendix of claims. The term "Try" should be --Tyr --. This typographical error was corrected herein.

> T is a peptide-forming residue of D-Glu, D-Asp, D-His, D-Lys, D-Tyr, or another ionizable peptide-forming D-amino acid; and
> d is a peptide-forming residue of L-Glu, L-Asp, L-His, L-Lys, L-Tyr, or another ionizable peptide-forming L-amino acid.

The examiner does not rely upon a reference.

GROUNDS OF REJECTION

Claims 4-8, 10-16, 18-23, 26 and 28-38 are rejected under 35 U.S.C. § 112, second paragraph, as the phrase "hydrophobic amino acid and glycine residues" is vague.

Claim 28 is rejected under 35 U.S.C. § 112, second paragraph, as the phrase "and other (or another) ionizable peptide forming D-amino acids" is vague.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, and to the respective positions articulated by the appellant and the examiner. We make reference to the examiner's Answer for the examiner's reasoning in support of the rejection. We further reference appellant's Brief for the appellant's arguments in favor of patentability.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

Claims 4-8, 10-16, 18-23, 26 and 28-38:

The examiner refers (Answer, page 4) to the Final Rejection[8] and states that "the state of the art is such that the [sic] undue experimentation would be required by the public." The Final Rejection states (pages 2-3) that "hydrophobic amino acid and glycine residues is vague; what positions and which hydrophobic amino acids? … Given that there are at least 4 hydrophobic naturally occurring amino acids, the number of permutations for the nanomer containing one glycine will be 48.1 = 65,536. That is, an experimenter would have to construct 65,536 nanomers [sic] determine which nanomers form the beta turn. The examiner submits that this effort constitutes too much experimentation."

The examiner did not use the correct legal standard to reach the conclusion that the claims are indefinite. The examiner's concerns regarding the amount of experimentation bespeaks more of a 35 U.S.C. § 112, first paragraph, enablement issue rather than one of indefiniteness under the second paragraph. However, here the examiner makes no mention of the first paragraph of section 112. Instead, the examiner bases his rejection on the second paragraph of section 112. We also note appellant's recognition (Brief, page 10, n. 4) that the statutory basis for this rejection is unclear. As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application

[8] Paper No. 44, mailed September 16, 1997.

disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art."

Appellant responds (e.g., Brief, pages 6-7) to the examiner's rejection by providing an extensive listing of United States Patents and including a number of United States Patents as Appendix B of the Brief.

Upon review of the United States Patents included in Appendix B we find, inter alia:

1. U.S. Patent No. 4,474,851, claim 1, "[a]n elastomeric composite material comprising: … wherein said repeating units comprise amino acid residues selected from the group consisting of hydrophobic amino acid and glycine residues and wherein said repeating units exist in a conformation having a ß-turn …."
2. U.S. Patent No. 4,589,882, claim 1, "[a] synthetic elastomeric copolymer, which comprises: … wherein said repeating units comprise amino acid residues selected from the group consisting of hydrophobic amino acid and glycine residues and said repeating units exist in a conformation having a ß-turn …."
3. U.S. Patent No. 4,870,055, claim 1 "[a method of increasing the modulus of elasticity of a bioelastomer containing repeating units … wherein said repeating units comprise amino acid residues selected from the group consisting of hydrophobic amino acid and glycine residues and wherein said repeating units exist in a conformation having a ß-turn…."

Appellant's claim 26 is drawn to "[a] drug delivery composition … comprising a synthetic bioelastic polypeptide polymer comprising repeating elastomeric units … wherein said repeating units comprise amino acid residues selected from the group consisting of hydrophobic amino acid and glycine residues and wherein said repeating units exist in a conformation having a ß-turn."

In light of the teachings of the prior art it does not appear that the phrase in question is vague, as suggested by the examiner. In addition, appellant refers (e.g., Brief, page 10) to sections of the specification to support the claims. The examiner makes no attempt in the Answer to address those sections identified by appellant. Therefore, it is unclear to us why the examiner maintains that the phrase "hydrophobic amino acid and glycine residues" is vague in view of appellant's specification, arguments and cited prior art (made of record as Appendix B of the Brief).

Therefore, on this record, we are compelled to find that the examiner failed to meet his burden of presenting the evidence necessary to sustain a rejection under 35 U.S.C. § 112, second paragraph.

Accordingly, we reverse the rejection of claims 4-8, 10-16, 18-23, 26 and 28-38 under 35 U.S.C. § 112, second paragraph.

Claim 28:

The examiner states (Answer, page 4) that "[i]n claim 28 'and other (or another) ionizable peptide forming D-amino acids' is vague; which ones?" In response appellant provides an argument to this rejection (Brief, pages 13-14) which includes a reference to United States Patent No. 5,255, 518 ('518). Claim 19 of '518 recites "… wherein said repeating unit having a ß-turn comprises a polypentapeptide unit of formula: -(VPFd)- wherein … F is a peptide-forming residue selected from the group consisting of … and other ionizable peptide forming D-amino acid residues."

The examiner argues (Final Rejection, page 3) that "[a]pplicant also contend that the phrase 'ionizable peptide forming amino acids' is not vague, referring to a passage disclosing Glu, Asp, Lys and His. It appears, then, that the phrase is superfluous because these amino acids are already recited for theta and delta in claim 28." Appellant refers to pages 12 and 13 of the specification to support his position that the claim is definite. At page 13, in addition to referring to Glu, Asp, Lys, and His (lines 26-27), appellant explains (lines 30-36) that:

> It is also possible to attach a moiety containing a functional group that undergoes a transition under conditions different from those attainable for naturally occurring amino acid side chains. For example a sulfate ester of Ser can be prepared in which sulfate ionizations will occur at a pH outside the range experienced by carboxylate groups.

The examiner is silent with respect to appellant's arguments. Again, it is unclear to us why the examiner maintains that the phrase is vague in view of appellant's specification, arguments and cited prior art (made of record as

Appendix B of the Brief). Therefore, on this record, we are compelled to find that the examiner failed to meet his burden of presenting the evidence necessary to sustain a rejection under 35 U.S.C. § 112, second paragraph.

Accordingly, we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

REVERSED

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SHERMAN D. WINTERS	)
Administrative Patent Judge	)
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	)
	) BOARD OF PATENT
WILLIAM F. SMITH	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
DONALD E. ADAMS	)
Administrative Patent Judge	)

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